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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/678,082	10/06/2003	Jacobus M. Lemmens	116.066	4414
<div>7590      07/16/2007</div> <div>Irving M. Fishman Cohen Tauber Spievack &amp; Wagner Suite 2400 420 Lexington Avenue New York, NY 10170</div>				
			EXAMINER KRASS, FREDERICK F	
			ART UNIT 1614	PAPER NUMBER
			MAIL DATE 07/16/2007	DELIVERY MODE PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/678,082	<b>Applicant(s)</b> LEMMENS ET AL.	
	<b>Examiner</b> Frederick Krass	<b>Art Unit</b> 1614	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 11 April 2007.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 51-59 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 51-59 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some    \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                       | 5) <input type="checkbox"/> Notice of Informal Patent Application                       |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

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### **Previous Rejections**

Unless specifically repeated/maintained infra, all previous rejections are withdrawn.

### **Claim Informality**

Claim 58 contains an obvious typographical error just before its end. Correction is required.

### **Obviousness Rejections**

Claims 51-59 were rejected as being unpatentable over Pathak et al (USP 6,113,944) in view of Benneker et al (USP 5,874,447) and Takado et al (USP 5,486,365).

This rejection is maintained.

Regarding Pathak et al, applicant argues that because “it is for the specific formulation therein that microcrystalline cellulose is optionally present or absent”, this would “lead one to the inclusion of microcrystalline cellulose” when its teachings were combined with the other references. This line of reasoning is not understood; there is no question that Pathak et al discloses compositions not containing microcrystalline cellulose. At best, this is a “piecemeal” analysis based on unsupported speculation.

Applicant also argues that Takado in no way “teaches or suggests to one of ordinary skill that they should expect success in achieving the results of the invention by replacing the dicalicum phosphate of Pathak with calcium hydrogen phosphate anhydrate.” It might be a good suggestion to try same, applicant argues, but that is not obviousness. The examiner does not agree. While the teachings of secondary reference are general in nature, they definitely suggest that there are advantages to using the anhydrate. That is sufficient motivation for obviousness; given the fact that the two fillers are so closely related, one would not reasonably infer that any expectation of success would be lacking, absent specific evidence to the contrary.

The examiner does agree, however, that the general teachings of Takado would not lead one to expect the specific improvements alleged by applicant (failure to develop pink color, and decreased bitterness). The examiner notes, however, that the specification merely alleges that unexpected results occur, without providing any factual verification of same. For instance, although the working examples demonstrate that applicant’s tablets did not turn pink upon storage under accelerated conditions (40 degrees C, 75 percent relative humidity), they do not provide any side-by-side testing versus a prior art tablet as a control. It is not clear that turning pink would be a problem at lower temperature and humidity, and the conditions used in the examples are not positively recited in any case. Moreover, the examples provide no data or observations concerning bitter taste or the masking of same. Where unexpected properties are generally alleged in a specification, the burden rests with applicant to factually verify same. See, e.g., In re Greenfield, 197 USPQ 227 (C.C.P.A. 1978).

**Action is Final**

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

**Correspondence**

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Frederick Krass whose telephone number is (571) 272-0580. The examiner can normally be reached at (571) 272-0580 on Monday through Friday from 9:30AM to 6:00PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, can be reached at (571) 272-0718. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Frederick Krass  
Primary Examiner  
Art Unit 1614

